JUN 19 2013

K130819

ATTACHMENT 19

510(k) Summary

K130819

510(k) Summary of Safety and Effectiveness

1. General information

- Applicant: Olympus Winter & Ibe GmbH
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  22045 Hamburg
  Germany

- Official Correspondent: Sheri L. Musgnung
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  Olympus Corporation of the Americas
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  Email: Sheri.Musgnung@Olympus.com
  Establishment Registration No.: 2429304

- Manufacturer: Olympus Winter & Ibe GmbH
  Kuehnstrasse 61
  22045 Hamburg / Germany

- Registration number: 9610773

- Contact person: Mr. Jan Schueller-Iwersen
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2. Device identification

- Proprietary name: CLL-V1, LED Light Source
- Common name: LED Light Source
- Regulations Number: 21 CFR 876.1500
- Regulatory class: Class II
- Product code: NTN, FCW
- Device panel: Gastroenterology/Urology

3 Predicate devices

Device Name:	Stryker L9000	Storz LED Nova 100 Cold Light Fountain
Manufacturer:	Stryker	Karl Storz
510(k) No.:	K082813	K091968

4 Description of device

The Olympus CLL-V1 is a desk top device which consists of a LED light source designed and intended to be used with Olympus-designated endoscopes, camera heads, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

5 Indications of use

This light source has been designed to be used with Olympus-designated endoscopes, camera heads, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

6 Comparison of Technological characteristics

LED is the advancing technology therefore the new light source CLL-V1 is based on the latest LED technology. The LED light source features a long lasting LED "bulb" with reduced energy consumption having no need for additional fan cooling therefore being silent in its use. The optimized light intensity allows higher contrast to existing Halogen bulbs resulting in higher brightness.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO-14971:2007.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following standards have been applied to the CLL-V1:

ISO 14971:2007
IEC 60601-1:1990 + A1:1993 + A2:1995 + A13:1996
IEC 60601-1-2:2007
IEC 60601-2-18:1996 +A1:2000
IEC 60601-1-6:2006

8 Conclusion

In summary, we believe the CLL-V1 is substantially equivalent with the predicate devices with respect to the general design approach, function, and the indications for use. The CLL-V1 raises no new concerns of safety or efficacy when compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 19, 2013

Olympus Winter and Ibe GmbH
% Olympus Corporation of the Americas
Ms. Sheri L. Musgnung
3500 Corporate Parkway – P.O. Box 610
Center Valley, Pennsylvania 18034-0610

Re: K130819
Trade/Device Name: CLL-V1 Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NTN, FCW
Dated: March, 22, 2013
Received: April 01, 2013

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130819

Device Name: CLL-V1, LED Light Source

Model Numbers: WA97020A

Indications For Use:

This light source has been designed to be used with Olympus-designated endoscopes, camera heads, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Neil R Ogden -S
2013.06.14 11:23:45 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K130819